IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA



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| **BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.,** **Plaintiffs,** | |
| **v.** | **Civil Action No. 1:17-cv-116-IMK** |
| **MYLAN PHARMACEUTICALS INC.,** **Defendant.** | |

**JOINT STIPULATION AND ORDER REGARDING INFRINGEMENT AND ASSERTED CLAIMS**

WHEREAS Plaintiffs Biogen International GmbH and Biogen MA Inc., (collectively "Plaintiffs" or "Biogen") and Defendant Mylan Pharmaceuticals Inc.[1] ("Defendant" or "Mylan") are Parties to this patent infringement case involving U.S. Patent Nos. 8,399,514 ("the '514 patent") and 7,619,001 ("the '001 patent");

WHEREAS the Parties wish to narrow the issues in this litigation;

WHEREAS Biogen has already stipulated that it will not assert claims 17-19 of the '514 patent against Mylan (*see* ECF 102);

THEREFORE, IT IS HEREBY STIPULATED, CONSENTED, AND AGREED TO by and between the Parties hereto as follows:

1. Mylan will not contend, argue or offer any proof in this case that the filing of Abbreviated New Drug Application ("ANDA") No. 210531 and any supplements or amendments thereto ("the Mylan ANDA") does not infringe claims 1-4, 6, 8-13, and 15-16 of the

[1] Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., a wholly owned subsidiary of Mylan N.V. For the purposes of this stipulation only, the term Mylan expressly encompasses other Mylan entities, as well as any future owners of the Mylan ANDA, if any.

'514 patent, if valid and enforceable, under 35 U.S.C. § 271(e)(2)(A). Mylan further will not contend, argue or offer any proof in this case that the commercial use, sale, or offer for sale of the drug product set forth in the Mylan ANDA would not infringe claims 1-4, 6, 8-13, and 15-16 of the '514 patent, if valid and enforceable, under 35 U.S.C. § 271. For the avoidance of doubt, Biogen need not offer any proof in this case, including at trial, that the filing of the Mylan ANDA infringes claims 1-4, 6, 8-13, and 15-16 of the '514 patent, if valid and enforceable, under 35 U.S.C. § 271.

2. Mylan consents to the entry of judgment in this action that the filing of the Mylan ANDA does infringe claims 1-4, 6, 8-13, and 15-16 of the '514 patent, if valid and enforceable, under 35 U.S.C. § 271(e)(2)(A). Mylan further consents to the entry of judgment in this action that the commercial use, sale, or offer for sale of the drug product set forth in the Mylan ANDA would infringe claims 1-4, 6, 8-13, and 15-16 of the '514 patent under 35 U.S.C. § 271, only to the extent those claims are not found to be invalid or unenforceable. For the avoidance of doubt, no relief shall be entered against Mylan unless the '514 patent has been found enforceable and valid.

3. Biogen stipulates and agrees that it does not and will not assert claims 5, 7, 14 and 20 of the '514 patent against Mylan, in this or any other proceeding, based on the Mylan ANDA to the extent that Mylan does not and will not materially change the active substance, formulation, or treatment schedule of its generic version of Tecfidera®.

4. Mylan will not contend, argue or offer any proof in this case that the filing of the Mylan ANDA does not infringe claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent, if valid and enforceable, under 35 U.S.C. § 271(e)(2)(A). Mylan further will not contend, argue or offer any proof in this case that the commercial manufacture sale, or offer for sale of the drug product set

forth in the Mylan ANDA would not infringe claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent, if valid and enforceable, under 35 U.S.C. § 271. For the avoidance of doubt, Biogen need not offer any proof in this case, including at trial, that the filing of the Mylan ANDA infringes claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent, if valid and enforceable, under 35 U.S.C. § 271.

5. Mylan consents to the entry of judgment in this action that the filing of the Mylan ANDA does infringe claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent, if valid and enforceable, under 35 U.S.C. § 271(e)(2)(A). Mylan further consents to the entry of judgment in this action that the commercial use, sale, or offer for sale of the drug product set forth in the Mylan ANDA would infringe claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent under 35 U.S.C. § 271 only to the extent those claims are not found to be invalid or unenforceable.

6. Biogen stipulates and agrees that it does not and will not assert claims 4-5,10-11, and 20-21 of the '001 patent against Mylan, in this or any other proceeding, based on the Mylan ANDA to the extent that Mylan does not and will not materially change the active substance, or formulation of its generic version of Tecfidera®.

7. Neither Mylan nor Biogen shall use this stipulation as an admission or waiver of claims and/or defenses, or in any manner, in any other forum, including but not limited to any other court, administrative agency or administrative tribunal.

8. Biogen and Mylan expressly reserve all rights to appeal any decision of this Court with respect to issues of validity and/or unenforceability of the '001 or '514 patents, or the entry of any such judgment as it pertains to validity and/or unenforceability of those patents' claims. For the avoidance of doubt, Mylan has consented to the entry of judgment in this action that the commercial use, sale, or offer for sale of the drug product set forth in the Mylan ANDA would

infringe claims 1-4, 6, 8-13, and 15-16 of the '514 patent and claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent under 35 U.S.C. § 271 only to the extent those claims are not found to be invalid or unenforceable, and therefore Mylan cannot appeal the issue of infringement as to these claims.

9. This Joint Stipulation does not relate in any way to Mylan's invalidity arguments and does not limit or otherwise affect Mylan's ability to defend against Biogen's infringement claims on any other ground of invalidity or unenforceability, including asserting any defense or counterclaims of invalidity or unenforceability for the '001 and '514 patents. Moreover, this Joint Stipulation is not an agreement as to the proper scope of an injunction, if any, or that one should be entered against Mylan. For the avoidance of doubt, this stipulation does not itself entitle Biogen to any injunctive relief, including an injunction pursuant to § 271(e)(4)(A), absent a finding by the Court that claims 1-4, 6, 8-13, and 15-16 of the '514 patent and claims 1-3, 6-9, 12-19, and 22-24 of the '001 patent are not invalid and that Biogen is otherwise entitled to an injunction.

10. This Joint Stipulation grants no rights to Mylan under any patents or other proprietary rights.

11. Nothing in this stipulation shall prejudice Mylan's right to oppose entry of any relief, including any order authorized by 35 U.S.C. § 271(e)(4)(A) and any injunctive relief authorized by 35 U.S.C. § 271(e)(4)(B), or entry of final judgment, based in whole or in part on an application of any estoppel under 35 U.S.C. § 315(e)(2) or to otherwise petition any court with respect to such relief except that Mylan shall not oppose any relief or judgment on the grounds of non-infringement.

12. Nothing in this Joint Stipulation limits Mylan's rights under 35 U.S.C. § 271(e)(1).

13. The parties reserve all other claims and defenses.

Respectfully submitted this 7 day of October, 2019.

**BIOGEN INTERNATIONAL GMBH and BIOGEN MA INC.**

***/s/ James F Companion***

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**MYLAN PHARMACEUTICALS INC.**

**/s/ Gordon H. Copland**

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So Ordered this 8th day of October 2019

Irene M. Keeley
United States District Judge